



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
UENO ET AL.

Appln. No.: 10/553,451

Group Art Unit: 1621

Confirmation No.: 6984

Examiner: Lao, Marialouisa

Filed: October 17, 2005

For: CRYSTALLINE PARAHYDROXYBENZOIC ACID ANHYDRIDE AND PROCESS
FOR PREPARING THE SAME

DECLARATION UNDER RULE 1.132

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Shigeji MORI, citizen of Japan and residing in Itami-shi, Hyogo, Japan declare and say as follows:

1. I am a graduate of Faculty of Pharmaceutical Sciences, Kanazawa University, Ishikawa, Japan in 1987, and received Master degree of Pharmaceutical Chemistry from Department of Pharmaceutical Chemistry, School of Pharmaceutical Sciences, Graduate School of Natural Science and Technology, Kanazawa University, Ishikawa, Japan in March, 1989.

2. Since April, 1989 up to this time, I have been an employee of Ueno Fine Chemicals Co., parent company of the assignee of the above-identified application, and have been engaged in the research and development work in the field of organic synthesis.

3. At present, I am a member of the Pharmaceutical Society of Japan

4. I am familiar with the subject matter of the above-identified application.

5. I have read the Office Action mailed January 18, 2007 and the references cited therein and am familiar with the subject matter thereof.

6. In order to show the product disclosed in Cocco's USP 4,814,498 is

different from those recited in Claims 8-10 of the above-identified application, following experiment has been done under my direction.

Experiment

Preparation of para-hydroxy benzoic acid according to Example of Cocco

Para-hydroxy benzoic acid was prepared along with the procedure disclosed in example of Cocco except for using in step (i) an aqueous solution of di-potassium salt of para-hydroxybenzoic acid which was obtained by mixing para-hydroxybenzoic acid (Ueno Fine Chemical Co.) 149.04g, 48wt% aqueous potassium hydroxide 252.50g and water 1043.62g.

After the methyl tert-butylether was distilled, the remaining aqueous para-hydroxy benzoic acid solution was gradually cooled from 100°C to 40°C. The precipitated para-hydroxy benzoic acid was filtered at 40°C to give 145.0g of crystalline para-hydroxy benzoic acid monohydrate. The water content in the crystalline product was determined by the Karl-Fischer method and confirmed to be 15.6wt%.

Thus obtained crystalline para-hydroxy benzoic acid monohydrate was dried at 70°C to give 120g of crystalline parahydroxy benzoic acid anhydride.

Physical properties of the product

Specific surface area, angle of repose, and compression ratio of the product obtained according to Example of the cited reference were determined in the manner disclosed in the Examples of the instant application. Results are shown in Table 1:

Table 1

| | Example of Cocco | This application |
|-----------------------|------------------------|--|
| specific surface area | 0.70 m ² /g | less than 0.3m ² /g (Claim 8) |
| angle of repose | 46.6° | less than 45° (Claim 9) |
| compression ratio | 20.7% | less than 10% (Claim 10) |

Discussion

As shown in the above table 1, the crystalline parahydroxy benzoic acid obtained according to the method of Cocco does not meet the requirements recited in instant Claims 8-10. Therefore, Claims 8-10 are not anticipated by Cocco.

7. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Dated this 13th day of April, 2007

Shigeji Mori
Shigeji MORI